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TITLE PAGE

Title:

Outcome of Patients Receiving a Continuous Flow Left Ventricular Assist Device – A Retrospective Single Center Study

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ABSTRACT

Objectives: We present the outcome of the first 80 patients receiving a continuous flow left ventricular assist device at Helsinki University Hospital between December 2011 and November 2018.

Design: This was a single-center retrospective study. We describe our patient management in detail. The primary end-points were death, heart transplantation, or pump explant. Data were reported in accordance with the Interagency Registry for Mechanical Circulatory Support protocol. All patients receiving an assist device during the study period were included in the data analysis.

Results: Mean patient age was 53 ± 12 years at implantation and 85 % were male. Most patients suffered from dilated (48%), or ischemic (40%) cardiomyopathy. One-third of patients were bridged with venoarterial extracorporeal membrane oxygenation to assist device implantation. Implant strategy was bridge to transplant or bridge to decision in most patients (88 %). Mean follow-up time on pump was 529 ± 467 days. Survival was 98%, 92%, 85%, 79% and 71% at 1, 3, 12, 24 and 36 months, respectively. Most common causes of death were multi-organ failure, right heart failure, or stroke. Only three patients (4%) had suspected pump thrombosis, two of which resolved with medical treatment and one resulting in death. Pump exchange or explant, were not performed in a single patient. Neurological events occurred in 18 %, non-disabling stroke in 8 %, and fatal stroke in 4% of the patients. The incidence of device-related infection was 10 %.

Conclusions: Survival rates were good, although one third of patients were bridged with temporary circulatory support. We report a high level of freedom from pump thrombosis, fatal stroke, and driveline infection.

Key words: CF LVAD, mortality, stroke, infection, pump thrombosis

INTRODUCTION

Heart transplantation (HTx) and durable mechanical circulatory support (MCS) are two effective treatment options for patients suffering from end stage heart failure (HF) refractory to medical or other surgical therapy. HTx has been the golden standard, offering better survival and quality of life [1]. The use of durable MCS with continuous flow left ventricle assist devices (CF LVAD) in treating advanced HF has been steadily growing due to limited availability of donor organs. Globally, LVAD therapy is increasingly being used for destination therapy (DT) [2].

The use of CF LVAD may be associated with several major complications. Neurological events are reported to occur in 17-38 % of patients and stroke in 10 -30 %. In recent randomized large trials on CF LVAD, 10% of patients had previous stroke, and 16 % - 19% had a history of transient ischemic attack [3 and 4]. The risk of pump thrombosis with CF LVADs is low but a high level of anticoagulation and antithrombotic treatment is necessary. Together with acquired coagulopathy, this increases the likelihood of bleeding. Driveline infections are associated with worse outcome and occur in 15 -24 % of patients. Functional class and survival are however significantly better in advanced HF patients on CF LVAD than patients on medical therapy [3-6].

At present, HTx seems to be the better option for treating end-stage HF. CF LVAD therapy in bridging patients to transplantation is reasonable and effective. In order to achieve comparable results also in DT patients, an improvement in long-term survival and reduction in complication rates must be demonstrated.

In this study, we report our single center results of CF LVAD use in Finland between 2011 and 2018.

METHODS

Study design

This single-center study was conducted at Helsinki University Hospital, the only heart transplantation and ventricular assist device-implanting center in Finland. Data was collected retrospectively and the primary end-points were death, HTx, or LVAD explant. Causes of death and adverse events were investigated by review of electronic medical records of the patients and defined according to the Interagency Registry for Mechanical

Circulatory Support (INTERMACS) manual of operations. The institutional review board, Helsinki University Hospital approved all data collection and analysis.

Study patients

Between December 2011 and November 2018, 80 patients were implanted with a CF LVAD, HVAD (HeartWare Inc., Framingham, MA, USA), which was the only available durable MCS during the study period in Finland. All patients were included in the study and followed through the end of January 2019.

Patient selection and management

Patients with end-stage HF refractory to optimal medical or other, medical device treatment were considered for LVAD implantation by our heart team consisting of a cardiac surgeon, cardiologist, and cardiac anesthesiologist. Other specialists were consulted as needed. Treatment strategy at implantation was bridge to decision (BTD), bridge to transplantation (BTT), DT, or rescue therapy. Patients were bridged due to critical illness, continuous deterioration or due to a reversible contraindication for direct transplantation such as pulmonary hypertension. Destination therapy was offered to elderly patients.

Our strategy to prevent perioperative right heart failure included preoperative reduction of fluid overload pharmacologically or by dialysis, intraoperative fluid ultrafiltration, and intravenous inotropic treatment usually with milrinone initiated at least 24 hours prior to LVAD implantation. Levosimendan was used in frequent flyers and some acute patients before bridging with ECMO but was not routinely administered preoperatively.

Implantations were performed by dedicated surgeons via a full sternotomy with the use of cardiopulmonary bypass and ventricular fibrillation without aortic cross clamping. Fibrillation offers better visualization of the LV cavity and inflow cannula tract due to less bleeding and motion of the heart. The outflow graft was directed to the right and sewn to the ascending aorta by tangential aortic clamping. The driveline was tunneled between the abdominal muscles and the posterior muscle fascia. An exit wound was created at the level of the umbilicus on the right. The velour-covered part of the driveline was left several centimeters subcutaneously. LVAD speed was gradually increased during weaning from bypass and the final speed (usually 2400-2700 rpm) was decided based on echocardiography findings, with the goal to have the interventricular septum close to the midline.

Post-operatively patients are monitored with a pulmonary artery catheter and the HVAD monitor to ensure adequate RV function and CF LVAD flow.

At present, all patients are postoperatively treated with milrinone, isoprenaline and inhaled nitric oxide, which are gradually weaned at the intensive care unit. Sildenafil treatment is started during weaning of nitric oxide. As soon as the vasopressors are weaned, heart failure medications are started including beta-blockers, ACE-inhibitors, loop diuretics and an aldosterone antagonist.

Heparin-infusion was started 24 hours after surgery with a target activated partial thromboplastin time (APTT) of 40-50 seconds, which was increased to 50-60 seconds on the second postoperative day, and continued until INR had been maintained within the therapeutic range for two days. Warfarin was started on the first postoperative day. A target INR of 2.5-3 was most commonly used but could be modified based on the status of the patient. Daily vitamin K supplementation was given to all patients in order to stabilize INR values. Aspirin was started during the implant hospitalization after removal of all chest tubes. The initial Aspirin dose was 100 mg and later adjusted based on patient status and platelet function tests with Multiplate®. Non-responders to Aspirin were switched to Clopidogrel. Patients routinely received low-dose simvastatin (10- 20 mg) therapy for endothelial protection.

Aspirin medication was stopped in patients with recurrent gastrointestinal bleeding. The INR target was lowered to 1.8-2.5. In bleeders, endoscopy of the gastrointestinal tract was performed at least once, including esophagogastroduodenoscopy and colonoscopy. Capsule-endoscopy or double-balloon endoscopy was used when necessary. Propranolol therapy was started in patients with angiodysplastic bowel lesions. Proton pump inhibitors were routinely used by all LVAD patients. Ocreotide therapy with daily subcutaneous injections was used in some cases and bevasitsumab therapy in an extremely challenging bleeder. Patients were also screened for iron-deficiency and received intravenous iron when necessary.

Postoperative antibiotic prophylaxis consisted of meropenem and vancomycin, which was stopped after removal of chest tubes. All patients received permanent trimethoprim/sulfamethoxazole or doxycycline prophylaxis once daily to prevent driveline infections.

After the implant hospitalization, all patients were followed by our LVAD coordinator and at our LVAD outpatient clinic every 1-3 months. Laboratory tests were performed every 1-3 weeks, including INR and hemolysis markers. Patients with INR values below the therapeutic range received low molecular weight heparin (LMWH). The driveline exit wound was inspected regularly and kept covered with sterile wound dressings or a chlorhexidine gluconate patch. The wound was treated by the patients and rinsed with normal tap water. Bacterial cultures were taken if infection was clinically suspected and treated accordingly. Hypertension was medicated to achieve a mean arterial pressure of 70-80 mmHg. For BTT patients, cardiac catheterization and other evaluation was performed, usually 3-6 months after implantation to determine right heart function and pulmonary vascular resistance. All patients were evaluated and treated by our physical therapist and by a nutritional therapist if necessary. Initial evaluation of some acute complications were performed in other participating hospitals. All patients with major complications were transferred to and managed at Helsinki University Hospital. Patients and local primary caregivers were encouraged to contact our LVAD coordinator or surgeon on call in cases of emergency. During the implant hospitalization, all patients were trained to follow their CF LVAD parameters, take care of the driveline wound and monitor clinical parameters such as weight and swellings.

Statistical methods

All statistical analyses were performed using SPSS 22 (IBMVR SPSSVR Statistics, version 22). Categorical variables are reported in frequencies and continuous variables as mean \pm standard deviation with range. Kaplan-Maier plots were used for survival analysis and the Log Rank test for determining significance. Fischer's exact test was used for contingency analysis. A p-value of less than 0.05 was considered significant in all analyses.

RESULTS

Baseline characteristics

Detailed baseline characteristics of the study cohort are presented in Table 1. Mean age was 53 ± 12 years (17-69 years). Patients were mostly male (85%) and suffered predominately from dilated (48%) or ischemic (40%) cardiomyopathy. Most of the patients were in INTERMACS class 2 or 3 (78%), and one-third of patients

(26/80) were bridged with ECMO to LVAD. Ten patients (13%) had a previous stroke. Only nine devices (11%) were implanted for destination therapy. Two patients had concomitant tricuspid valve repair.

Outcomes

After surgery, the patients required mechanical ventilation for 3.4 ± 6.9 days (1-49) and intravenous inotrope therapy for 6.8 ± 4.2 days (1-20). Mean length of ICU stay was 10.8 ± 9.1 days (1-52) and mean length of hospital stay was 34.3 ± 17.9 days (10-103). Patients on preoperative ECMO required longer hospital stays than the ones without. However, the difference was not significant (40 ± 21 days vs 32 ± 16 days, $p=0.11$). Seventy-three patients (91%) were discharged home, one patient (1%) to another hospital and 6 (8%) patients died during the implant hospitalization (Table 2).

Nine patients (11%) were re-operated within 48 hours due to bleeding, and two patients (3%) required reoperation due to aortic dissection. Both aortic dissection patients had intra-aortic balloon pump (IABP) prior to LVAD implantation. Both patients were treated with endovascular repair of the descending thoracic aorta. One of them also required reconstruction of the ascending aorta and proximal arch.

Survival after LVAD implantation is presented in Figure 1. Mean follow-up was 752 ± 654 days (1-2618) and time on LVAD was 529 ± 467 days (1-2254) (Table 3). Survival was 98%, 92%, 85%, 79% and 71% at 1, 3, 12, 24, and 36 months, respectively. We did not observe any statistically significant effect of gender, disease, strategy, or preoperative ECMO-treatment on survival with Kaplan-Meier analysis. Younger patients seemed to do better but the difference remained statistically insignificant (Figure 2). In the whole cohort, 28 patients (36 %) have been transplanted out of which two thereafter died. One heart transplant recipient died due to primary graft dysfunction and the other due to mesothelioma 4 years after transplantation. Time to transplantation was 663 ± 463 days (143-2247). Eighteen (23 %) died while on LVAD, and the mean time to death was 398 ± 436 days (1-1470). Thirty-four (43 %) patients currently have a pump with an average follow-up of 484 ± 463 days (75-2254).

Causes of death are presented in Table 3. The most common cause of death was multi-organ failure (MOF) (4), followed by right heart failure (RHF) (3), stroke (3), amiodarone-induced acute respiratory distress syndrome (ARDS) (2), and sepsis (2). One patient died from pump thrombosis and consequent heart failure

after initial successful thrombolysis. Other causes consisted of suicide (1), anaphylaxis (1) and device stop due to accidental removal of all power sources (1). Two of the patients died during the first 30 days after implantation. The first patient was on ECMO due to postcardiotomy cardiogenic shock and underwent LVAD implantation in MOF as the last attempt to rescue him, but he died in fulminant liver failure and hemodynamic collapse within a few hours after surgery. The second patient with multiple drug hypersensitivity was readmitted to hospital, given intravenous antibiotics, and died due to anaphylactic shock on day 22 after LVAD implantation.

Adverse events

Two patients required temporary RVAD support at the time of LVAD implantation. Additionally, severe RHF was observed in 13 other patients (16 %) on average 95 ± 142 days (2-483) after implantation (Table 4). Nine patients with RHF suffered from dilated cardiomyopathy and four patients from ischemic cardiomyopathy. Statistically, there was no difference between the two groups ($p=0.23$). In 10 patients, RHF resolved with conservative treatment, including intravenous diuretics, ultrafiltration, and milrinone infusion. Three patients (4 %) developed severe right heart failure leading to MOF and death. Fourteen patients (18 %) had respiratory failure leading to prolonged mechanical ventilation and death in two patients (3 %). Both deaths were associated with amiodarone-induced ARDS.

There was 14 patients (18 %) with neurological events that occurred 320 ± 361 days (24-1230) after implantation. Three patients (4%) suffered from fatal stroke; two of them had previous strokes. Six more patients (8 %) suffered from milder strokes with 3 or less points on the modified Rankin scale. Two patients were invasively treated with interventional embolectomy and thrombus aspiration. The other stroke patients were treated conservatively. Four patients (5 %) suffered from transient ischemic attacks. One patient (1 %) had a non-disabling subarachnoid bleeding. One more patient (1 %) had a non-disabling spontaneous intracerebral hemorrhage. Peripheral embolism to the upper extremity was observed in one patient (1 %) and was successfully treated with embolectomy (Table 4).

We did not perform a single pump exchange during the study period and observed only three cases of suspected pump thrombosis (4 %) diagnosed by increase in plasma lactate dehydrogenase and abnormal pump

parameters. One asymptomatic patient was successfully treated with heparin infusion. Two patients required thrombolysis therapy. One died after incomplete thrombolysis and re-thrombosis. The patient was not considered for urgent transplantation or pump exchange due to poor overall condition. The other patient was transplanted shortly after successful thrombolysis (Table 4). One patient (1 %) suffered from hemolysis without changes in pump parameters and was managed with intravenous heparin.

We observed pump malfunction in four patients. A destination therapy patient accidentally cut the driveline with scissors and the pump was stopped for 4 hours. The driveline was repaired and the patient was discharged home without any complications. Controllers were exchanged in three patients (4 %) due to minor malfunction without compromise of circulatory support.

Driveline exit-wound infection was observed in 7 patients (9 %). One patient had a deep driveline infection (1 %). Mean time to the first driveline infection was 493 ± 499 days (52-1306). Species causing driveline infections were staphylococcus aureus, staphylococcus epidermidis, streptococcus viridans, stenotrophomonas maltophilia, moraxella species, and pseudomonas aeruginosa. Three patients (4 %) had driveline infections with positive blood cultures. One patient (1 %) died from sepsis caused by driveline infection. Non-pump related causes of major infection and sepsis were more frequent. Thirty-four major infection events was observed in the study population (Table 4).

Early postoperative bleeding requiring surgery occurred in 9 patients (11 %). Major bleeding later than 48 hours after LVAD implantation occurred in 20% of the patients. Mean time to first bleeding was 61 ± 91 days (6-378). Gastrointestinal bleeding was diagnosed in 11 patients (14 %). Other bleedings were mediastinal (6 %) or pleural (1 %). Thirty-two major bleeding events were documented; none of them was fatal (Table 4). Figure 3 demonstrates freedom from bleeding, infection and the composite outcome of death, disabling stroke or LVAD explant.

After discharge home, 40 patients needed to be readmitted (50%). Mean time to the first readmission was 214 ± 252 days (22-1230). Total number of readmissions was 97. Twenty patients needed only one readmission, 7 patients were re-hospitalized twice and 13 patients required more than two readmissions. Most common causes of readmission were non-pump related infection (19), gastrointestinal bleeding (23), right heart failure

(13), and stroke (11). Pump malfunction requiring speed re-adjustment or controller exchange (n=9), driveline infection (n=8), and arrhythmia (n=4) were less frequent. Twelve other readmissions were due to other infrequent causes.

Functional outcomes

Most of the patients suffered preoperatively from NYHA class IV symptoms (84 %). Already 3 months after LVAD implantation patients functional class improved and at 1 year, most patients were in NYHA class I (73 %), while few patients were in NYHA classes II (19 %) and III (8 %).

Baseline 6-minute walk test (6MWT) distances were extremely low 136 ± 184 m (0-570) due to a high percentage of patients on ECMO (33 %) before implantation. Ambulatory patients' 6MWT-result was 352 ± 112 m (160-570). During the first postoperative year 6MWT distance increased to 521 ± 120 m (227-710). Compared to age and sex-matched healthy subjects, the patients walked 75 % of the reference distance at 3 months, 80 % at 6 months and at later time points around 85 % of the reference value.

DISCUSSION

In this study, we present our single center experience of CF LVAD therapy in patients with end-stage heart failure. Most patients were bridged to transplantation. In the recent IMACS and INTERMACS reports, survival for all CF LVAD patients has been 81-83 %, 71-73 % and 62-62 % at 1, 2 and 3 years [2 and 5]. In a follow-up report of the REVOLVE study, investigating long-term outcome in BTT HVAD patients, survival was 84, 78 % and 68 % during the first three years [7]. Our survival rates are similar. Based on ISHLT reports regarding survival after heart transplantation performed after 2009, the survival rate at one year is 85% [8]. This figure is also comparable to our results. Both heart transplantation and LVAD treatment offer significantly better outcome for end-stage heart failure patients than medical treatment alone [6].

Most Finnish patients are treated as BTD or BTT. In Finland, during 2016-2018, HTx was performed in 5.2 patients per million population while CF LVAD was implanted in 3.4 patients per million population. One in two HTx, is currently performed from CF LVAD in Finland [9]. The average waiting time for heart

transplantation on LVAD was just under two years, which is similar to waiting times for our patients without MCS. In 2018, we observed a 10 % mortality on our transplant waiting list (data available on www.scandiatransplant.org). About one third of our LVAD patients needed preoperatively ECMO-support in cardiogenic shock. These patients would have died without LVAD implantation or high urgency heart transplantation. Therefore, LVAD implantation offered these patients the chance to receive a transplant. Additionally, the patients without need for ECMO support prior to LVAD implantation improved their physical condition during LVAD support, as evidenced by improved 6MWT results. The downside to transplanting patients on CF LVAD is the need for redo surgery and potential acquired bleeding disorders. We currently have no data on long-term outcome of HTx after LVAD therapy. However, a previous report has shown comparable results to HTx recipients without prior LVAD therapy [10].

HTx patients in Finland have 1-year and 5-year survival rates of over 90 % and 85 %, respectively. The key in improving CF LVAD therapy is to extend the already achieved early survival benefit and improve long-term outcome, with the goal of achieving similar survival rates as for HTx [8]. This might not be possible in elderly DT patients. Expanding DT strategy to younger patients is also controversial in a country like Finland since organ availability through the national and Scandiatransplant organizations are relatively good. We currently have an average survival after heart transplantation in Finland of approximately 14 years. One way to improve combined survival in BTT patients would be to increase bridging times and thereby extend cumulative survival. This approach was challenged by a recent report [11] and still requires more data on long-term survival in our patients.

The leading cause of death in our study was MOF followed by RHF, stroke, ARDS and sepsis. Earlier studies with CF LVAD devices have reported lower RHF mortality [1 and 12] but in a recent report the incidence was 6 % [4]. Not surprisingly, patients with dilated cardiomyopathy had more episodes of RHF in this study. This difference was, however, not significant and was not related to cause of death. RHF and MOF is often a continuum, and the previous results could be related to differences in reporting since there is no general recommendation on how to report causes of death in MCS studies. In this study, most cases of RHF occurred more than 1 month after implantation. This could imply that these patients should have been managed more aggressively with LVAD speed adjustment, diuretics and fluid restriction.

Patients with heart failure often have several cardiovascular co-morbidities and are at risk for having strokes regardless of whether they are on CF LVAD or not, as seen by our preoperative 13 % stroke incidence. During the first two years after implantation, stroke occurs in 10-30 % of patients and disabling stroke in 1-7 % [1, 2, and 3]. So far, infection and hypertension have most strongly been related to stroke risk [13 and 14]. These are factors we are trying to combat aggressively in our patients and report low numbers of both driveline infections and strokes. Although, we generally keep the INR target over 2.5, we have seen very few intracranial bleedings and our overall bleeding rate was relatively low. Fatal strokes were seen in only three patients. The patients with non-disabling strokes were rehabilitated effectively and evaluated for transplantation as early as possible. New strokes were not observed in these patients.

Bleeding, hemolysis and thrombosis are all related [15 and 16]. In the present study, we had very few cases of hemolysis and suspected pump thrombosis. This was achieved by keeping INR levels mainly over 2.5 and by performing platelet function tests to make sure patients responded to antiplatelet therapy. The regular analysis of hemolysis markers allowed us to react to early signs of hemolysis. We treated all three cases of thrombosis medically and two of them successfully, although a recent meta-analysis showed clearly better survival in surgically treated patients [17]. Major bleeding occurred in 20 % and were mostly gastrointestinal. None of the bleedings were fatal and only one spontaneous ICH was life threatening. The patients that died after stroke all had hemorrhagic strokes and it is possible that our high level of antiplatelet and anticoagulant therapy increased this risk to some extent. Previous large CF LVAD trials have reported higher incidences of bleeding (28 – 60 %) and pump thrombosis (1-14 %) than in the present study [1, 3 and 4].

We report a low incidence of major device-related infection. This was achieved by careful patient monitoring and wound care together with prophylactic antibiotic therapy. Functional improvement of patients was seen early after hospital discharge and supports previous evidence of beneficial effects of CF LVAD treatment in terminal heart failure [3, 4 and 6].

CONCLUSIONS

We show good survival rates of mainly BTT/BTD patients on CF LVAD, although one-third of patients were bridged with ECMO to LVAD. We report a low incidence of stroke, pump thrombosis and driveline infection. This was achieved through close surveillance of the patients and personal adjustment of anticoagulant and antiplatelet therapy and permanent infection prophylaxis. Attention was kept on controlling hypertension, wound care and early signs of pump thrombosis.

LIMITATIONS

This is a retrospective and single-center study. Data collection of end-points and adverse events was done in accordance with general guidelines by the authors but inter-observer bias of the data cannot be excluded. Some data might have been unavailable due to post-operative treatment of the patients in other hospitals. The study population followed for over two years was small and this could influence the results. Direct comparison to other trials can therefore not necessarily be made.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare.

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Table 1. Baseline characteristics of patients receiving a CF LVAD.

Characteristics		LVAD patients, n=80
Age (years)		53±12 (17-69)
	Distribution	
	17-39	12 (15)
	40-59	42 (53)
	60-69	26 (33)
Male gender		68 (85)
BMI (kg/m ²)		25.6 (17.0-37.2)
Diagnosis		
	Ischemic	32 (40)
	Dilatated	38 (48)
	Inflammatory	3 (4)
	Other	7 (9)
LVEF (%)		18±7 (9-40)
NYHA		
	class III	13 (16)
	class IV	67 (84)
Intermacs		
	1	1 (1)
	2	23 (29)
	3	39 (49)
	4	13 (16)
	5	3 (4)
	6	0 (0)
	7	1 (1)
6MWT (m)		136 ±184 (0-570)
Arrhythmia		28 (35)
Frequent flyer		13 (16)
Previous stroke		10 (13)
Preoperative situation		
	At home	21 (26)
	Hospitalized	27 (34)
	ICU	32 (40)
Renal replacement therapy		5 (6)
Mechanical ventilation		27 (34)
Preoperative mechanical circulatory support		
	ECMO	24 (30)
	IABP	3 (4)
	Both	2 (3)
Prior cardiac surgery		
	<30 days	5 (6)
	>30 days	9 (11)
Strategy		
	Bridge to transplant/ decision	70 (88)
	Destination therapy	9 (11)
	Rescue	1 (1)

Continuous values presented as **mean±SD** (range), categorical as **n** (%). CF LVAD= continuous flow left ventricular assist device, BMI = body mass index, LVEF = left ventricle ejection fraction, NYHA = New York Heart Association functional class, 6MWT = 6-minute walk test, ICU = intensive care unit, ECMO= extracorporeal membrane oxygenation, IABP = intra-aortic balloon pump.

Table 2. Postoperative course after CF LVAD implantation.

Mechanical ventilation (days)	3.4±6.9 (1-49)
Intravenous inotrope therapy (days)	6.8±4.2 (1-20)
Early complications (within 48 h)	
bleeding requiring surgery	9 (11)
aortic dissection	2 (3)
death	1 (1)
Renal replacement therapy	16 (20)
Temporary RVAD	2 (3)
ICU stay (days)	10.8±9.1 (1-52)
Hospital stay (days)	34.3±17.9 (10-103)
Discharge	
Home	73 (91)
another hospital	1 (1)
in-hospital death	6 (8)

Continuous values presented as **mean±SD** (range), categorical as **n** (%). CF LAVS = continuous flow left ventricular assist device, RVAD = right ventricular assist device, ICU = intensive care unit.

Table 3. Outcomes and causes of death after CF LVAD implantation.

Total follow-up time (days)	752±654 (1-2618)
Time on pump (days)	529±467 (1-2254)
Time to transplant (days)	663±463 (143-2247)
Time to death (days)	398±436 (1-1470)
Cause of death	18 (23)
MOF	4 (5)
Right heart failure	3 (4)
Stroke	3 (4)
ARDS	2 (3)
Sepsis	2 (3)
Pump thrombosis	1 (1)
Other	3 (4)

Continuous values presented as **mean±SD** (range), categorical as **n** (%). CF LVAD = continuous flow left ventricular assist device, MOF = multi-organ failure, ARDS = acute respiratory distress syndrome.

Table 4. Adverse events after CF LVAD implantation.

Severe right heart failure	15 (19)
RVAD requirement	2 (3)
Inotropic support	13 (16)
Neurological dysfunction	14 (18)
Non-disabling stroke	6 (8)
Fatal stroke	3 (4)
Transient ischemic attack	4 (5)
ICH	2 (3)
Neurological events	17
Peripheral thromboembolism	1 (1)
Suspected pump thrombosis	3 (4)
Major infection	21 (26)
Driveline	7 (9)
Pump/pocket	1 (1)
Sepsis	8 (10)
Device-related sepsis	3 (4)
Other	8 (10)
Infection events	34
Respiratory failure	15 (19)
Major bleeding	16 (20)
Gastrointestinal	11 (14)
Mediastinal	5 (6)
Pleural	1 (1)
Bleeding events	32

Values presented as **n (%)**. CF LVAD = continuous flow left ventricular assist device, RVAD = right ventricular assist device, ICH = intracerebral hemorrhage.

FIGURES

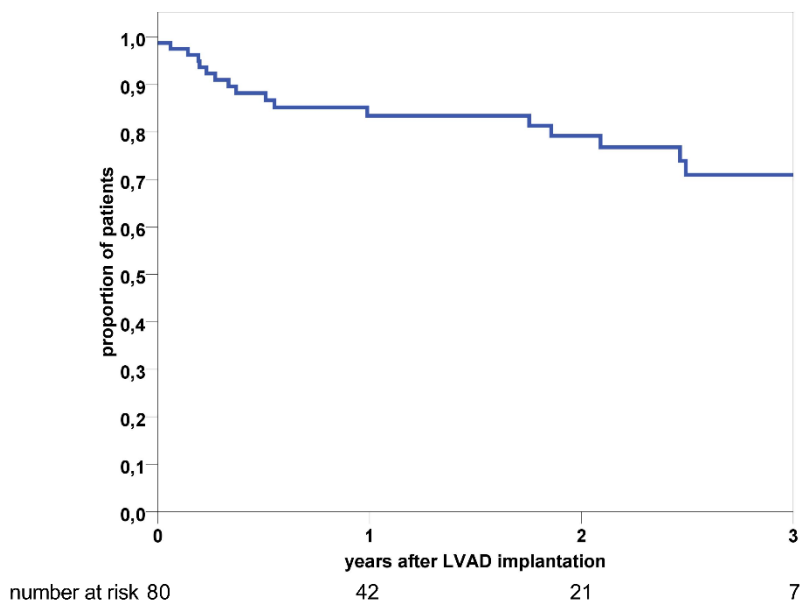


Figure 1. Kaplan-Meier analysis for overall survival in all 80 CF LVAD patients.

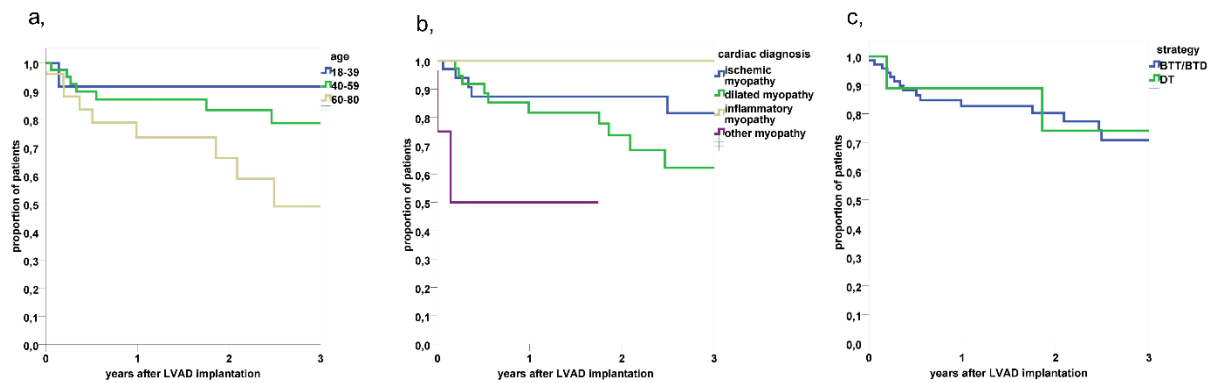


Figure 2. Kaplan-Meier survival analysis for age (a), diagnosis (b) and strategy (c). Differences between groups were insignificant with Log-Rank tests. BTT/BTD= bridge do transplantation/decision, DT= destination therapy.

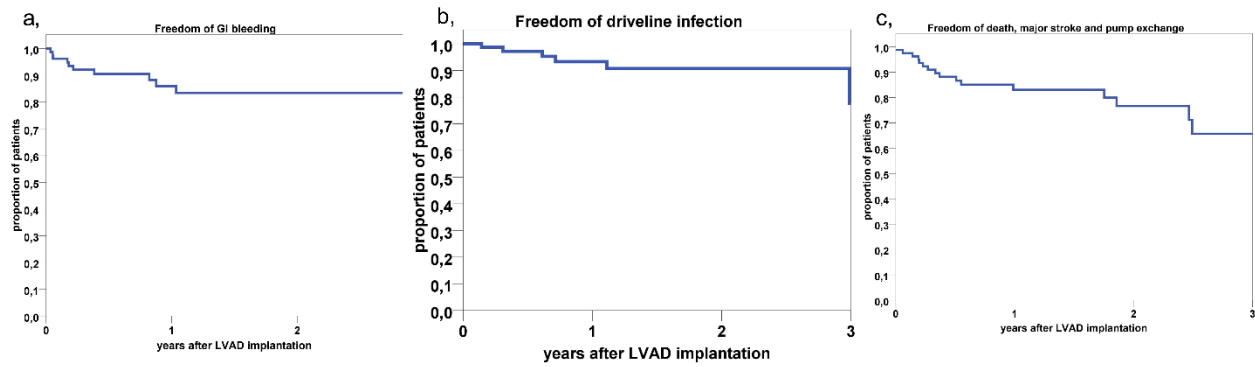


Figure 3. Kaplan-Meier analysis of freedom of gastrointestinal bleeding (a), driveline infection (b) and composite of death, major stroke or pump exchange (c).